

REMARKS

An Amendment in response to the Office Action dated November 17, 2003, accompanied by a Request for Continuing Examination and a Three-Month Extension of Time, was previously filed. This communication is filed in response to the Notice of Non-Compliant Amendment dated Jun 1, 2004. In this communication, the status identifier "previously presented" has been used instead of "previously added".

The present claims are claims 20-35.

As discussed in the present specification, this invention provides hydrogel materials possessing a very desirable combination of properties for contact lens applications, including low modulus and high oxygen permeability. See, for example, the Summary of the Invention. Independent claims 20 and 27 have been amended to define such properties. Support for the values recited in these claims can be found in the examples in Tables 2 to 5.

Claims 20-35 were rejected under 35 USC 102(b) as anticipated by, or in the alternative under 35 USC 103(a) as obvious over, Kunzler et al. (US 5,387,662). Reconsideration is requested.

As previously pointed out by Applicants, all examples of Kunzler et al. employ a (meth)acrylated endcapped fluorosiloxane-containing monomer, whereas the present claims require a vinyl carbonate endcapped polysiloxane monomer containing a fluorinated side chain. More specifically, the copolymers disclosed in Tables 1 to 4 of Kunzler et al. all employ a (meth)acrylate endcapped fluorosiloxane – please see the syntheses described in Examples 2 to 5.

The Examiner has correctly pointed out the teachings of Kunzler et al. are not limited to (meth)acrylated fluorosiloxanes. Specifically, the Examiner has noted the definition of "A" in Formula (III) of Kunzler et al., as well as the monomer disclosed at column 7, line 55.

Nonetheless, Kunzler et al. does not describe within the meaning of Section 102, or suggest within the meaning of Section 103(a), hydrogels as presently claimed. First, no copolymer examples of Kunzler et al. employ a vinyl carbonate endcapped polysiloxane monomer containing a fluorinated side chain. Second, no copolymer examples of Kunzler et al. having the combination of physical properties defined in the claims.

For example, in Table 1 of Kunzler et al., the hydrogels having a water content of at least 20 weight percent exhibited a high oxygen permeability (Dk), but also exhibited a high modulus.

As another example, in Table 4, most hydrogels had a low modulus, but also exhibited a low oxygen permeability. As yet another example, in Table 3, most hydrogels had a high oxygen permeability, but again exhibited a high modulus -- for the last entry in Table 3, the hydrogel has a low modulus, but also a low oxygen permeability.

Stated differently, the presently claimed invention provides hydrogels exhibiting improved properties over the preferred materials of Kunzler et al. Although the general teachings of Kunzler et al. include vinyl carbonate endcapped monomers, Kunzler et al. does not suggest that substituting the vinyl carbonate endcapped monomers would lead to the improved combination of properties.

Claims 27 and 29-31 were rejected under 102(b) as anticipated by, or in the alternative under 35 USC 103(a) as obvious over, Nandu et al. (US 5,260,000). Reconsideration is requested.

Nandu et al. discloses the production of contact lenses. Formulation A of Nandu et al. includes V2D25, a vinyl carbonate endcapped monomer, but this monomer lacks a fluorine sidechain (see V2D25 at column 4, lines 31-39). Thus, similar to Kunzler et al., no example of Nandu et al. includes a vinyl carbonate endcapped polysiloxane monomer containing a fluorinated side chain.

In fact, the lens-forming monomers of Nandu et al. Formulation A correspond to those in Applicant's commercial contact lenses sold under the trademark "PureVision". These lenses have a water content of 36 weight percent ($\pm 3\%$), and a modulus ranging from 70-150 g/mm². Historical oxygen permeability measurements of these lenses range from 80.7 to 101.0 Barrers, averaging 91.1 (std. dev. 6.0).

In summary, Nandu et al. does not suggest hydrogels having the monomeric components and combination of properties defined in the present claims.

Finally, Applicant notes the following for the Examiner's consideration. Different techniques exist to measure oxygen permeability. Some techniques, such as defined in ANSI Z80.20.1998, are polarographic methods. Other techniques, such as defined in US 5,817,924, are coulometric methods. For any given method, reproducibility of that method varies -- as a rule of thumb, oxygen permeability measurements may vary $\pm 20\%$. As an example, as pointed out above, historical oxygen permeability measurements of PureVision lenses, using both the cited

polarographic and coulometric methods, range from 80.7 to 101.0 Barrers, averaging 91.1 (std. dev. 6.0). Also, as pointed out above, PureVision lenses have a water content of 36 weight percent ($\pm 3\%$), and a modulus ranging from 70-150 g/mm².

A favorable action on the merits is requested. The Examiner is invited to contact the undersigned to resolve any remaining issues.

Respectfully submitted,



John E. Thomas
Registration No. 34,070
BAUSCH & LOMB INCORPORATED
One Bausch & Lomb Place
Rochester, NY 14604-2701
Telephone: (585) 338-8969

Dated: June 10, 2004

2460Amdt-2